REMARKS

As the result of the response filed on June 6, 2007, claims 20-30 are pending in the application. Claims 20-28 are finally rejected, but no action was taken with regard to claims 29 and 30.

Amendments to the Claims Were Not Considered

Applicant's response of June 6, 2007 amended claims 20, 22, 24, 26 and 27 and added new claims 29 and 30. The Office Action Summary (PTOL-326) and Status of the Claims in the final office action acknowledge that the final office action is in response to the June 6 response; however, only claims 20-28 were indicated as being pending and no action was taken with respect to claims 29 and 30.

Furthermore, certain recitations in claims 20 and 24 are again objected to in the final office action as not having support in the specification, but those recitations are no longer in the claims as the result of amendments made in the 6/6/07 response. Similarly, in the Examiner's rejection of claim 20 under 35 USC 102(b), reference is made to an element of claim 20 ("providing the respiratory circuit with a lower volume flow of gas than the pressure generating circuit") that was deleted from claim 20 as the result of amendments made in the 6/6/07 response. Applicants respectfully submit that these references to the unamended claims by the Examiner indicate that Applicants' amendment of 6/6/07 was not entered and that the amended claims were not examined. Accordingly, the Examiner failed to properly reconsider and examine the application after the Applicants' 6/6/07 response, as required under 37 CFR 1.112.

For the above reasons, Applicants respectfully request that the final rejection of the claims be reconsidered and withdrawn. Since the application is currently under final rejection, a Request for Continuing Examination is submitted herewith.

Claim Rejection Under 35 USC 102(b)

Claim 20 is rejected as anticipated by Riggs et al U.S. Pat. No. 5,355,872 ("Riggs"). Riggs teaches a method of delivering a nebulized medicant to a patient using the nebulizer apparatus of Fig. 1, which comprises 2 gas-carrying circuits. A first circuit is a breathing circuit that comprises inhalation respiratory pathway 26 and exhalation respiratory pathway 28. Inhalation pathway 26 supplies periodic, breath-sustaining pulses of pressurized gas from ventilator 10 through tube 12, nebulizer device 48, and leg 34 of "Y"-shaped connector 32 into

endotracheal tube 24 and to patient 30 (col. 9, lines 35-39). Exhalation pathway 28 returns exhalation flow from patient 30 along leg 36 of connector 32 through tube 16 to ventilator 10. (col. 9, lines 40-46) The second circuit supplies pressurized nebulizing gas along fluid pathway 26' from gas source 44 through flow meter 40 and tube 42 to nebulizer 20. (col. 9, lines 47-65) Nebulizer 20 comprises a nebulizing device 48 which contains medicant and is constructed and arranged to produce nebulized medicant by dispersing liquid medicant in the carrier gas passing through nebulizer device 48 from pathway 26' at a specific flow rate governed by flow meter 40. (col. 7, lines 11-18) The aerosolized medicant produced by nebulizing device 48 is then passed through the breathing circuit to endotracheal tube 24 connected to the respiratory system of patient 30.

The Examiner contends that the method disclosed by Riggs comprises a step wherein the pressure-assisted breathing system of Fig. 1 is provided with a respiratory circuit 26' adapted to be coupled to a patient interface device, as recited in claim 20. Applicants respectfully disagree. Pathway 26' is not a respiratory circuit (it provides pressurized carrier gas to nebulizer 20 to allow nebulizer 20 to produce nebulized medicant), and pathway 26' is clearly not adapted to be coupled to endotracheal tube 24. Furthermore, claim 20 (as amended by Applicants' response of 6/6/07) contains the limitation that the pressure-generating circuit contains a gas flow of sufficiently high volume to maintain continuous positive pressure in the system. As described above, the breathing circuit disclosed by Riggs supplies periodic pulses of pressurized gas from ventilator 10, not continuous positive pressure.

Still further, the method of claim 20 (as amended) comprises the step of introducing the aerosolized medicament into the second lower gas flow in the respiratory circuit to avoid dilution of the aerosolized medicament that is delivered to the patient's respiratory system. Riggs clearly teaches that the nebulized medicant formed in nebulizer 20 (by dispersing the liquid medicament in the carrier gas provided by pathway 26') is discharged directly into the gas provided in inhalation pathway 26. Therefore, even if the gas flow in pathway 26' could be of lower volume than the gas flow in pathway 26 as suggested by the Examiner, Riggs teaches introducing the aerosolized medicament into the higher volume flow of pathway 26, which would cause dilution of the aerosolized medicament delivered to the patient's respiratory system.

For the reasons discussed above, Riggs does not disclose each and every element of claim 20 and therefore does not anticipate claim 20 under 35 USC 102. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections Under 35 USC 103

Only claims 21-23, 25-26 and 28 are identified in the general statement on page 4 of the office action as being rejected as obvious over Riggs in view of Davison et al GB 2,272,389 ("Davison"). However, independent claim 24 and dependent claim 27 are apparently also subject to the same rejection because the Examiner applies the rejection to claim 24 in the last paragraph on page 5 and to claim 27 in the last paragraph on page 6. Dependent claims 29 and 30 are not subject to any rejection in the office action; however, Riggs clearly discloses the limitations of claims 29 and 30; i.e., an endotracheal tube as a patient interface device. Therefore, Applicants have treated all claims as being subject to the obviousness rejection in the following discussion.

As discussed above, Riggs does not teach each of the elements of claim 20 upon which claims 21-23 are dependent, e.g. Riggs does not teach the step of introducing aerosolized medicament into the respiratory circuit of a pressure-assisted breathing system to avoid dilution of the aerosolized medicament delivered to the patient's respiratory system. Davison discloses apparatus including a vibrating aperture-type nebulizer that introduces aerosolized medicament into a duct 32 communicating between an air inlet 33 and an outlet port 34 of a non-pressurized dispensing apparatus 30. Therefore, even assuming *arguendo* that it would have been obvious to substitute the vibrating aperture-type aerosol generator of Davison for the nebulizer of Riggs as proposed by the Examiner, the combination does not result in the invention of claims 21-23. For this reason, reconsideration and withdrawal of the rejection is respectfully requested.

Claim 24 is nonobvious for the same reasons discussed in connection with claims 20-23. In addition, claim 24 specifically recites that the respiratory circuit connects the pressure-generating circuit to the patient interface device. Riggs teaches that pathway 26', which the Examiner contends corresponds to a respiratory circuit, connects nebulizer 20 to gas source 44 through flow meter 40 (See Fig. 1). Pathway 26'never connects to the patient interface device 24. Furthermore, Riggs discloses that liquid surfactant aerosolized in the nebulizer is passed through the breathing circuit (inhalation pathway 26) to a pulmonary situs of the patient (e.g. col.

7, lines 26-27; col. 9, line 66-col. 10, line 4). Therefore, in the method disclosed by Riggs, the aerosolized surfactant delivered to the patient through the patient interface device is subject to dilution by the relatively high volume flow in the breathing circuit, in contrast to the claimed method wherein such dilution is avoided.

As the Examiner states, Riggs further fails to disclose a CPAP system as claimed in claim 24. However, the Examiner then erroneously concludes that "Riggs' device is well capable of providing a continuous positive airway pressure using 106" (office action, page 5, last paragraph). Contrary to the Examiner's contention, Riggs discloses that "a continuous flow system 106 provides substantially continuous delivery of fluid to nebulizer vial 50 to maintain a volume of liquid at an adequate and essentially unchanging level in reservoir 72." (col. 10, lines 8-12). Therefore, system 106 carries a supply of liquid to the nebulizer, and is incapable of providing a continuous supply of air to maintain positive airway pressure in the system. As discussed above, Riggs actually teaches away from claim 24 because the breathing circuit disclosed by Riggs supplies periodic pulses of pressurized gas from ventilator 10, not continuous positive pressure. Claims 25-30 are dependent on claim 24 and are also nonobvious for the same reasons as discussed in connection with claim 24.

In light of the above, reconsideration and withdrawal of the rejection is respectfully requested.

Claim Objections

As indicated above, the recitations objected to by the Examiner were deleted from claims 20 and 24 by the response of 6/6/07. In addition, there are no grounds for the objections because Fig. 1 and the accompanying description are included in the specification only to compare a method wherein aerosolized medicament 9 is introduced into the high-volume flow of gas 8 in the pressure-generating circuit P with the claimed method, which is shown in Fig. 2. The claimed method is supported, for example, in paragraph 0025 wherein aerosolized medicament 9 is introduced into lower volume inspiratory flow 18 in respiratory circuit R in accordance with the claims. In light of the foregoing explanation, Applicants believe that the objections have been overcome.

CONCLUSION

For the reasons set forth above, Applicants contend that all of the claims are in condition for allowance. Accordingly, applicants respectfully request that the examiner reconsider and withdraw the outstanding rejections of the claims, and issue a formal Notice of Allowance at an early date.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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